K130535

AgaMatrix.

APR 17 2013

AgaMatrix, Inc. • 7C Raymond Avenue • Salem, NH 03079 USA

510(k) Summary

This summary of 510k) substantial equivalence is being submitted in accordance with the requirements of 21 CFR 807.92.

Prepared: March 28, 2013

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Device Name: Trade/Proprietary Name: iBGStar Blood Glucose Monitoring System
Common Name: Glucose Test System

Product Name: iBGStar Diabetes Manager Application
Common Name: Diabetes Management Software

Device Classification:

Product Code	Classification	Regulation Section	Panel
NBW – system, test, blood glucose, over the counter	Class II	21 CFR 862.1345	75, Clinical Chemistry
JQP - Calculator/data processing module for clinical use.	Class I	21 CFR 862.2100	75, Clinical Chemistry

Predicate Device:

iBGStar Blood Glucose Monitoring System, iBGStar Diabetes Manager Application, 510(k) K103544

Device Description:

The iBGStar Blood Glucose Monitoring System (BGMS) consists of:

- iBGStar Blood Glucose Meter
- BGStar Test Strips
- BGStar Control Solution

The iBGStar Diabetes Manager Application (DMA) is an optional software accessory for the iBGStar Blood Glucose Monitoring System. It is a digital logbook and diabetes tool designed to operate using an iPhone or iPod touch. An individual can manually enter blood glucose readings or can download readings directly to the DMA installed on an iPhone or iPod touch from the iBGStar meter.

Labeling and Intended Use:

The iBGStar BGMS Owner's guide has been edited to include instructions on how to connect the meter to a device with the Lightning adapter. The iBGStar BGMS carton has been updated to include a statement that the meter will work with the iPhone 5 and iPod touch 5th generation when using the Lightning adapter.

Intended Use

The iBGStar™ Blood Glucose Monitoring System is intended for the quantitative measurement of blood glucose levels in fresh capillary whole blood samples drawn from the fingertip, palms (at the base of the thumb), or forearms. It is intended to be used by a single patient and should not be shared. The iBGStar™ Blood Glucose Monitoring System is intended for self testing outside the body (*in vitro* diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The iBGstar Blood Glucose Monitoring System is not for the diagnosis of, or screening for diabetes, and is not intended for use with neonates.

The iBGStar Diabetes Manager Application is intended for use in the home with the capability of sending glucose readings through email to an individual's healthcare professional in the review, analysis and evaluation of glucose test results to support an effective diabetes management program. It is an optional data management software accessory for use with the iBGStar Blood Glucose Monitoring System.

Technological Characteristics:

There were no changes to the fundamental scientific technology.

Comparison to Predicate:

Blood Glucose Monitoring System (meter, strips, controls)

There have been no modifications to the iBGStar BGMS to allow it to operate with the iPhone 5 and iPod touch 5th generation. The Meter, Test Strips and Control Solution are identical to the previously cleared system. The iBGStar BGMS has the all the same technological and performance characteristics as the predicate. There were minor modifications to the labeling for the iBGStar BGMS to clarify the use of the meter with the iPhone 5 and iPod touch 5th generation. The table below illustrates the same intended use and characteristics between the predicate device and the candidate device (no differences between predicate and candidate).

Similarities		
Characteristic	**iBGStar BGMS (predicate)**	**iBGStar BGMS (candidate)**
Indications for Use	Blood Glucose Monitoring	Same
Intended Use	Home Use	Same
Calibration	No coding required	Same
Test Principle/Enzyme	Glucose Oxidase	Same
Control Levels	Two levels	Same
System Characteristics	Operating Temp, Test Time, Test Range, Sample Size, Test strips, Control Solution	Same
Backlight	No	Same
Number of results stored	300	Same
Power Source	Polymer lithium-ion rechargeable batteries	Same
Optional Software accessory	iBGStar Diabetes Manager Application	Same
Differences		
None		

Diabetes Manager Application

The iBGStar DMA has the same intended use as the previously cleared system. The iBGStar DMA has the all the same technological and performance characteristics as the predicate. There is no modification to the labeling for the iBGStar DMA. To transfer glucose readings from the iBGStar meter to the iBGStar DMA which has been downloaded on Apple's new iPhone 5 and/or iPod touch 5th generation, an Apple Lightning to 30-pin Adapter or the Apple Lightning to 30-pin Adapter (0.2m) is required The table below lists the similarities and differences between candidate and predicate device.

Similarities		
Characteristic	**iBGStar Diabetes Manager App (predicate) to iPhone 3G,3GS,4, 4S iPod touch 2,3,4**	**iBGStar Diabetes Manager App (candidate) to iPhone 5 and iPod touch 5**
Indications for Use	Download glucose readings to a data management system to aid in the effective management of diabetes.	Same
Intended Use	Home Use	Same
Management Tools	Logbook and Trend Charts	Same
Upload To	Device compatible with the iPhone Operating System platform	Same
Differences		
Characteristic	**iBGStar Diabetes Manager App (predicate) to iPhone 3G,3GS,4, 4S iPod touch 2,3,4**	**iBGStar Diabetes Manager App (candidate) to iPhone 5 and iPod touch 5**
Transfer of Glucose Readings	No connector needed **(see Figure 1)**	Apple Lightning to 30-pin Adapter **(see Figure 2)** or Apple Lightning to 30-pin Adapter (0.2m) cable **(see Figure 3)**

Figure 1: iPhone to iBGStar-no connector

Figure 2: Apple Lightning to 30-pin Adapter

Figure 3: Apple Lightning to 30-pin Adapter (0.2m) Cable

Assessment of Performance:

Disinfection Study:

Per pre-submission Q120016 (See Attachment 2 of original submission), FDA recommended that disinfection and robustness testing be performed on the new components.

Disinfection testing on the surface materials of the iPhone 5, iPod touch 5, Apple Lightning to 30-pin Adapter, and Apple Lightning to 30-pin Adapter (0.2m) cable was performed by an outside lab. The results with PDI® Super Sani-Cloth® Germicidal Disposable Wipes with EPA number 9480-4 demonstrated complete inactivation of live virus (see Attachments 3 and 4 of original submission).

Robustness testing was performed with the iPhone 5, iPod touch 5th generation, Lightning to 30-pin Adapter, and Lightning to 30-pin Adapter (0.2m) cable using the PDI® Super Sani-Cloth® Germicidal Disposable Wipes with EPA number 9480-4. The results demonstrate there was no change in performance or material of the tested devices at the conclusion of the disinfection and robustness testing which consisted of 260 cleaning/disinfection cycles designed to simulate 5 years of use (see Attachments 5,6 and 7 of original submission).

Verification and Validation:

Verification and validation protocols were successfully executed to validate the use of the Apple Lightning to 30-pin Adapter and the Apple Lightning to 30-pin Adapter (0.2m) cable with the iBGStar DMA. Results demonstrate substantial equivalence to the predicate system.

Human Factors Study:

A human factors study (see Attachments 8 and 9 of original submission) was conducted to evaluate the ability of users to connect and transfer readings from the iBGStar meter to the iBGStar DMA via the new Apple Lightning to 30-pin Adapter and the Apple Lightning to 30-pin Adapter (0.2m) cable. Results demonstrate substantial equivalence to the predicate system.

Conclusion:

The results of the disinfection and robustness testing and the performance assessments demonstrated that the candidate iBGStar Blood Glucose Monitoring System and the iBGStar Diabetes Manager Application using the Lightning to 30-pin Adapter or 30-pin Adapter (0.2m) cable performs in a substantially equivalent manner to that of the predicate. We conclude that the iBGStar Blood Glucose Monitoring system and the iBGStar Diabetes Manager Application are substantially equivalent the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 17, 2013

AgaMatrix, Inc.
C/O William H. McGrail
7C Raymond Ave
SALEM NH 03079

Re: K130535
Trade/Device Name: iBGStar Blood Glucose Monitoring System
iBGStar Diabetes Manager Application
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW, JQP
Dated: March 28, 2013
Received: April 02, 2013

Dear Mr. McGrail:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson -S for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): k130535

Device Name: iBGStar Blood Glucose Monitoring System, iBGStar Diabetes Manager Application

Indications for Use:

The iBGStar™ Blood Glucose Monitoring System

The iBGStar™ Blood Glucose Monitoring System is intended for the quantitative measurement of blood glucose levels from fresh capillary whole blood samples drawn from the fingertip, palms (at the base of the thumb), or forearms. It is intended to be used by a single patient and should not be shared. The iBGStar™ Blood Glucose Monitoring System is intended for self testing outside the body (*in vitro* diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The iBGStar™ Blood Glucose Monitoring System is not for the diagnosis of, or screening for diabetes, and is not intended for use with neonates.

The iBGStar Diabetes Manager Application – Home Use

The iBGStar Diabetes Manager Application is intended for use in the home with the capability of sending glucose readings through email to an individual's healthcare professional in the review, analysis and evaluation of glucose test results to support an effective diabetes management program. It is an optional data management software accessory for use with the iBGStar Blood Glucose Monitoring System.

Prescription Use __X__ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use __X___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Devices and Radiologic Health (OIR)

Katherine Serrano

Division Sign-Off
Office of In Vitro Diagnostic Devices and Radiologic Health

510(k) k130535

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